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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/644,293 Confirmation No.: 6668
Applicant: Liotta, *et al.*
Filed: August 20, 2003
TC/A.AU.: To be assigned
Examiner: To be assigned
Docket No.: 18085.105119 EMU 134 DIV4
Customer No.: 20786
Title: Method of Resolution and Antiviral Activity of 1,3-Oxathiolane Nucleoside Enantiomers

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

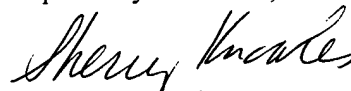
Information Disclosure Statement

Sir:

The citation of information on the accompanying Form PTO-1449, "List of Art Cited by Applicant" is made pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98. A copy of each of the following references is enclosed: BU, BV, BW, BX, BY, CN and CAD. Each of the remaining references was cited during prosecution of the parent application, U.S.S.N. 10/073,734, therefore as permitted under § 1.98(d) copies are not provided, however copies can be provided upon request. The citation of this information does not constitute an admission of priority or that any cited item is available as a reference, or a waiver of any right the applicant may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

Applicant does not believe any fees are due because this paper is submitted before the mailing of a first Office action on the merits, as under 37 C.F.R. § 1.97(b)(3). However, the Commissioner is hereby authorized to charge any fees due or credit any overpayment, to Deposit Account No. 11-0980.

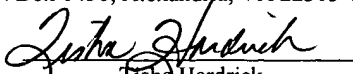
Respectfully submitted,


Sherry M. Knowles, Esq.
Reg. No. 33,052

Dated: June 24, 2004
King & Spalding, LLP
191 Peachtree Street, N.E., Atlanta, GA 30303
Office: (404)572-4600/ Fax: 404-572-5145

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on June 24, 2004.


Tisha Hardrick

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 1 of 8				Complete if Known	
				Application Number	10/644,293
				Filing Date	August 20, 2003
				First Named Inventor	Liotta, et al.
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	18085.105119 EMU 134 DIV4

3339248_5.DOC

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. 1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code 2 (if known)			
	AA	3,116,268		Farago	12-31-1963	
	AB	3,116,282		Hunter	12-31-1963	
	AC	3,553,192		Gauri	01-05-1971	
	AD	4,000,137		Dvonch, <i>et al.</i>	12-28-1976	
	AE	4,336,381		Nagata, <i>et al.</i>	06-22-1982	
	AF	4,861,759		Mitsuya, <i>et al.</i>	08-29-1989	
	AG	4,879,277		Mitsuya, <i>et al.</i>	11-07-1989	
	AH	4,900,828		Belica, <i>et al.</i>	02-13-1990	
	AI	4,916,122		Chu, <i>et al.</i>	04-10-1990	
	AJ	4,963,533		de Clercq, <i>et al.</i>	10-16-1990	
	AK	4,968,674		Taniyama, <i>et al.</i>	11-06-1990	
	AL	5,011,774		Farina, <i>et al.</i>	04-30-1991	
	AM	5,041,449		Belleau, <i>et al.</i>	08-20-1991	
	AN	5,047,407		Belleau, <i>et al.</i>	09-10-1991	
	AO	5,059,690		Zahler, <i>et al.</i>	10-22-1991	
	AP	5,071,983		Koszalka, <i>et al.</i>	12-10-1991	
	AQ	5,089,500		Daluge	02-18-1992	
	AR	5,151,426		Belleau, <i>etal.</i>	09-29-1992	
	AS	5,179,104		Chu, <i>etal.</i>	01-12-1993	
	AT	5,185,437		Koszalka, <i>et al.</i>	02-09-1993	
	AU	5,204,466		Liotta, <i>et al.</i>	04-20-1993	
	AV	5,210,085		Liotta, <i>etal.</i>	05-11-1993	
	AW	5,215,971		Datema, <i>et al.</i>	06-01-1993	
	AX	5,234,913		Furman, Jr., <i>etal.</i>	08-10-1993	
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	AAA	5,270,315		Belleau, <i>et al.</i>	12-14-1993	
	AAB	5,276,151		Liotta	01-04-1994	
	AAC	5,409,906		Datema, <i>et al.</i>	04-25-1995	
	AAD	5,432,165		Adair, <i>et al.</i>	07-11-1995	
	AAE	5,444,063		Schinazi	08-22-1995	
	AAF	5,446,029		Eriksson, <i>et al.</i>	08-29-1995	
	AAG	5,466,806		Belleau, <i>et al.</i>	11-14-1995	

Examiner Signature		Date Con- sidered	
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

2

of

8

Complete if Known

Application Number

10/644,293

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August 20, 2003

First Named Inventor

Liotta, *et al.*

Group Art Unit

Unassigned

Examiner Name

Unassigned

Attorney Docket Number

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U.S. PATENT DOCUMENTS

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		Number	Kind Code ² (if known)			
	BA	5,486,520		Belleau, <i>et al.</i>	01-23-1996	
	BB	5,521,161		Malley, <i>et al.</i>	05-28-1996	
	BC	5,532,246		Belleau, <i>et al.</i>	07-02-1996	
	BD	5,538,975		Dionne	07-23-1996	
	BE	5,539,116		Liotta and Choi	07-23-1996	
	BF	5,587,480		Belleau, <i>et al.</i>	12-24-1996	
	BG	5,618,820		Dionne	04-08-1997	
	BH	5,663,320		Mansour et al.	09-02-1997	
	BI	5,684,164		Belleau	11-04-1997	
	BJ	5,693,787		Mansour	12-02-1997	
	BK	5,696,254		Mansour	12-09-1997	
	BL	5,700,937		Liotta, <i>et al.</i>	12-23-1997	
	BM	5,728,575		Liotta, <i>et al.</i>	03-17-1998	
	BN	5,744,596		Mansour	04-28-1998	
	BO	5,756,706		Mansour	05-26-1998	
	BP	5,814,639		Liotta, <i>et al.</i>	09-29-1998	
	BQ	5,827,727		Liotta, <i>et al.</i>	10-27-1998	
	BR	5,892,025		Liotta	04-06-1999	
	BS	5,914,331		Liotta, <i>et al.</i>	06-22-1999	
	BT	5,914,400		Liotta, <i>et al.</i>	06-22-1999	
	BU	6,069,252		Liotta, <i>et al.</i>	05-30-2000	
	BV	6,153,751		Liotta, <i>et al.</i>	11-28-2000	
	BW	6,346,627		Liotta, <i>et al.</i>	02-12-2002	
	BX	6,642,245		Liotta, <i>et al.</i>	11-04-2003	
	BY	6,703,396		Liotta <i>et al.</i>	03-09-2004	

FOREIGN PATENT DOCUMENTS

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	BZ	WO	88/07532		Holmes; Nycomed A.S.	10-06-1988		
	BAA	WO	88/08001		Aktiebolaget Astra	10-20-1988		
	BAB	WO	90/12023		Walker, <i>et al.</i>	10-18-1990		

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Sheet **3** of **8****Complete if Known**

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		Office ³	Number	Kind Code ² (if known)				
	CA	WO	91/09124		Biotech Australia Pty Ltd	06-27-1991		
	CB	WO	91/11186	A1	Emory University	08-08-1991		
	CC	WO	91/17159		IAF Biochem. Int'l Inc.	11-14-1991		
	CD	WO	92/06102		Medivir A.B.	04-16-1992		
	CE	WO	92/08727		Consiglio...; Menarini...	05-29-1992		
	CF	WO	92/10496		U. Georgia Res. Found.	06-25-1992		
	CG	WO	92/10497		U. Georgia R.F.; Emory	06-25-1992		
	CH	WO	92/14729	A1	Emory University	09-03-1992		
	CI	WO	92/14743	A2	Emory University	09-03-1992		
	CJ	WO	92/15308		Wellcome Foundation Ltd	09-17-1992		
	CK	WO	92/15309		Wellcome Foundation Ltd	09-17-1992		
	CL	WO	92/18517		Yale U.; U. Georgia R. F.	10-29-1992		
	CM	WO	92/21676		Glaxo Group Ltd.	12-10-1992		
	CN	WO	93/03027		Biochem Pharma Inc.	02-18-1993		
	CO	WO	93/23021		Wellcome Foundation Ltd	11-25-1993		
	CP	WO	94/04154		U. Georgia R.F.; Emory	03-03-1994		
	CQ	WO	94/09793		Emory University	05-11-1994		
	CR	WO	94/14456		Biochem Pharma Inc.	07-07-1994		
	CS	WO	94/14802		Biochem Pharma Inc.	07-07-1994		
	CT	WO	94/14831		University of Alberta	07-07-1994		
	CU	WO	94/27590		United States (Sec. HHS)	12-08-1994		
	CV	WO	94/27616		Yale University	12-08-1994		
	CW	WO	95/07086		Emory, C.N.R.S., UAB	03-16-1995		
	CX	WO	95/07287		C.N.R.S.	03-16-1995		
	CY	WO	95/18137		Genta, Inc.	07-06-1995		
	CZ	WO	95/20595		U. Georgia R. F.; Yale U.	08-03-1995		
	CAA	WO	95/21183		Acid (Canada) Inc.	08-10-1995		
	CAB	WO	96/07413		U. Georgia R. F.; Yale U.	03-14-1996		
	CAC	WO	96/40164		Emory, UAB, C.N.R.S.	12-19-1996		
	CAD	WO	00/22157	A1	Altus Biologics Inc.	04-20-2000		
	CAE	EP	0 206 497		Wellcome Foundation Ltd	12-30-1986		
	CAF	EP	0 217 580		Wellcome Foundation Ltd	04-08-1987		
	CAG	EP	0 285 884		Bristol-Myers Co.	10-12-1988		

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Application Number				10/644,293	
Filing Date				August 20, 2003	
First Named Inventor				Liotta, et al.	
Group Art Unit				Unassigned	
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Attorney Docket Number				18085.105119 EMU 134 DIV4	
Sheet	4	of	8		

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		Office ³	Number	Kind Code ² (if known)				
	DA	EP	0 337 713		Biochem Pharma Inc.	10-18-1989		
	DB	EP	0 350 811		E.R. Squibb & Sons, Inc.	01-17-1990		
	DC	EP	0 352 248		Medivir Aktiebolag	01-24-1990		
	DD	EP	0 357 009		G.D. Searle & Co.	03-07-1990		
	DE	EP	0 361 831		Wellcome Foundation Ltd	04-04-1990		
	DF	EP	0 375 329		Wellcome Foundation Ltd	06-27-1990		
	DG	EP	0 382 526		IAF Biochem Int'l Inc.	08-16-1990		
	DH	EP	0 409 227		Akad. Wissensch. DDR	01-23-1991		
	DI	EP	0 421 636		E.R. Squibb & Sons, Inc.	04-10-1991		
	DJ	EP	0 433 898		Abbott Laboratories	06-26-1991		
	DK	EP	0 494 119		IAF Biochem Int'l Inc.	07-08-1992		
	DL	EP	0 515 144		Biochem Pharma Inc.	11-25-1992		
	DM	EP	0 515 156		Biochem Pharma Inc.	11-25-1992		
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	DO	EP	0 526 253		Biochem Pharma Inc.	02-03-1993		
	DP	NL	8901258		Stichting Rega te Leuven	12-17-1990		
	DQ	JP	07109221	B4	Wellcome Foundation Ltd	11-22-1995		
	DR	AU	630913	B2	Biochem Pharma Inc.	11-12-1992		
	DS	AU	665187	B2	Emory University	12-21-1995		
	DT	NZ	0238017	A	Biochem Pharma Inc.	06-27-1994		

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Sheet	5	of	8		

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	EA	ABOBO, <i>et al.</i> , "Pharmacokinetics of 2', 3' -Dideoxy-5-fluoro-3'-thiacytidine in Rats," <i>J. of Pharmaceutical Sciences</i> , 83(1):96-99 (1994)
	EB	AGRANT and BIEDERMANN, "Intellectual Property and Chirality: Patentability of Enantiomers of Racemic Drugs in a Racemic Switch Scenario," Institute for Advanced Studies at The Hebrew University of Jerusalem, <i>8th Chirality Conference</i> , Edinburgh, UK (07/02/1996)
	EC	ALLTECH ASSOCIATES, INC., "The Separation of Optical Isomers," <i>Bulletin #87</i> .
	ED	BEACH, J.W., <i>et al.</i> , "Synthesis of Enantiomerically Pure (2'R,5'S)-(1)-l-[2-hydroxymethyl]-oxathiolan-5-yl] Cytosine as a Potent Antiviral Agent Against Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)," <i>J. Org. Chem.</i> , 57:2217-2219 (1992)
	EE	BELLEAU, B., <i>et al.</i> , "Design and Activity of a Novel Class of Nucleoside Analogs Effective Against HIV-1," <i>International Conference on AIDS</i> , Montreal, Quebec, Canada, June 4-9, 1989
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	EG	CHANG, C.-N., <i>et al.</i> , "Deoxycytidine Deaminase-resistant Stereoisomer Is the Active Form of (±)-2',3'-Dideoxy-3'-thiacytidine in the Inhibition of Hepatitis B Virus Replication," <i>The Journal of Biological Chemistry</i> , 267(20):13938-13942 (1992)
	EH	CHANG, C.-N., <i>et al.</i> , "Biochemical Pharmacology of (+) and (-)-2',3'-Dideoxy-3'-Thiacytidine as Anti-Hepatitis B Virus Agents," <i>J. Biol. Chem.</i> , 267(31):22414-22420 (1992)
	EI	CHOI, <i>et al.</i> , "In Situ Complexation Directs the Stereochemistry of N-Glycosylation in the Synthesis of Oxathiolanyl and Dioxolanyl Nucleoside Analogues," <i>J. Am. Chem. Soc.</i> , 113:9377-9379 (1991)
	EJ	CHOI, <i>et al.</i> , "Synthesis, Anti-Human Immunodeficiency Virus, and Anti-Hepatitis B Virus Activity of Pyrimidine Oxathiolane Nucleosides," <i>Bioorgan. and Med. Chem. Lett.</i> , 3(4):693-696 (1993)
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	EL	COATES, <i>et al.</i> , "The Separated Enantiomers of 2'-Deoxy-3'-thiacytidine(BCH-189) Both Inhibit Human Immunodeficiency Virus Replication <i>In Vitro</i> ," <i>Antimicrob. Agents Chemother.</i> , 36(1):202-205 (1992)
	EM	CONDREAY, <i>et al.</i> , "Evaluation of the Potent Anti-Hepatitis B Virus Agent (-) <i>cis</i> -5-Fluoro-1-[2-(Hydroxymethyl)-1,3-Oxathiolan-5-yl]Cytosine in a Novel <i>In Vivo</i> Model," <i>Antimicrobial Agents and Chemotherapy</i> , 38(3):616-619 (March 1994)
	EN	CONNOLLY, <i>et al.</i> , "Minireview: Antiretroviral Therapy: Reverse Transcriptase Inhibition," <i>Antimicrobial Agents and Chemotherapy</i> , 36(2):245-254 (1992)
	EO	DOONG, Shin-Lian., <i>et al.</i> , "Inhibition of the Replication of Hepatitis B Virus <i>in vitro</i> by 2',3'-Dideoxy-3'-Thiacytidine and Related Analogues," <i>Natl. Acad. Sci. USA</i> , 88:8495-8499 (1991)

Examiner Signature	Date Considered
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Sheet 6 of 8

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	FA	FEORINO, et al., "Prevention of activation of HIV-1 by antiviral agents in OM-10.1 cells," <i>Antiviral Chem. & Chemotherapy</i> , 4(1):55-63 (1993)
	FB	FRICK, et al., "Pharmacokinetics, Oral Bioavailability, and Metabolic Disposition in Rats of (-)-cis-5-Fluoro-1-[2-(Hydroxymethyl)-1,3-Oxathiolan-5-yl] Cytosine, a Nucleoside Analog Active against Human Immunodeficiency Virus and Hepatitis B Virus," <i>Antimicrobial Agents and Chemotherapy</i> , 37(11):2285-2292 (1993)
	FC	FRICK, et al., "Pharmacokinetics, Oral Bioavailability, and Metabolism in Mice and Cynomolgus Monkeys of (2'R,5'S)-cis-5-Fluoro-1-[2-(Hydroxymethyl)-1,3-Oxathiolan-5-yl] Cytosine, an Agent Active against Human Immunodeficiency Virus and Human Hepatitis B Virus," <i>Antimicrobial Agents and Chemotherapy</i> , 38(12):2722-2729 (1994)
	FD	FURMAN, et al., "The Anti-Hepatitis B Virus Activities, Cytotoxicities, and Anabolic Profiles of the (-) and (+) Enantiomers of cis-5-Fluoro-1-[2-(Hydroxymethyl)-1,3-Oxathiolan-5-yl]Cytosine," <i>Antimicrobial Agents and Chemotherapy</i> , 36(12):2686-2692 (1992)
	FE	HERDEWIJN, et al., "Resolution of Aristeromycin Enantiomers," <i>J. Med. Chem.</i> , 28:1385-1386 (1985).
	FF	HOONG, et al., "Enzyme-Mediated Enantioselective Preparation of Pure Enantiomers of the Antiviral Agent 2',3'-Dideoxy-5-fluoro-3'-thiacytidine (FTC) and Related Compounds," <i>J. Org. Chem.</i> , 57:5563-5565 (1992)
	FG	HUTCHINSON, "New approaches to the synthesis of antiviral nucleosides," <i>Trends in Biotech.</i> , 8(12):348-353 (1990)
	FH	IMAI, et al., "Studies on Phosphorylation. IV. Selective Phosphorylation of the Primary Hydroxyl Group in Nucleosides," <i>J. of Org. Chem.</i> , 34(6):1547-1550 (1969)
	FI	ITO, et al., "Chirally Selective Synthesis of Sugar Moiety of Nucleosides by Chemicoenzymatic Approach: L- and D-Riboses, Showdomycin, and Cordycepin," <i>J. Am. Chem. Soc.</i> , 103:6739-6741 (1981)
	FJ	JEONG, et al., "Structure-Activity Relationships of β -D-(2S, 5R)- and α -D-(2S, 5S)-1,3 Oxathiolanyl-Nucleosides as Potential Anti-HIV Agents," <i>J. Med. Chem.</i> , 36:2627-2638 (1993)
	FK	JEONG, L., et al., "Asymmetric Synthesis and Biological Evaluation of β -L-(2R,5S)- and α -L (2R-5R)-1,3-Oxathiolane-Pyrimidine and -Purine Nucleosides and Potential Anti-HIV Agents," <i>J. Med. Chem.</i> , 36(2):181-195 (1993)
	FL	KIM, et al., "Asymmetric Synthesis of 1,3-Dioxolane-Pyrimidine Nucleosides and Their Anti-HIV Activity," <i>J. Med. Chem.</i> , 35:1987-1995 (1992)
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Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/644,293
				Filing Date	August 20, 2003
				First Named Inventor	Liotta, <i>et al.</i>
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
(use as many sheets as necessary)				Attorney Docket Number	18085.105119 EMU 134 DIV4
Sheet	7	of	8		

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	GA	KIM, <i>et al.</i> , "Potent Anti-HIV and Anti-HBV Activities of (-)-L-β-Dioxolane-C and (+)-L-β-Dioxolane-T and Their Asymmetric Syntheses," <i>Tetrahedron Lett.</i> , 33(46):6899-6902 (1992)
	GB	KRENITSKY, <i>et al.</i> , "An Enzymic Synthesis of Purine D-arabinonucleosides," <i>Carbohydrate Research</i> , 97:139-146 (1981)
	GC	MAHMOUDIAN, <i>et al.</i> , "Enzymatic Production of Optically Pure (2'R-cis)-2'-deoxy-3' thiacytidine (3TC, Lamivudine): A Potent Anti-HIV Agent," <i>Enzyme Microb. Technol.</i> , 15:749-755 (September 1993), published by the Glaxo Group Research.
	GD	MANSOUR, <i>et al.</i> , "Anti-Human Immunodeficiency Virus and Anti-Hepatitis-B Virus Activities and Toxicities of the Enantiomers of 2'-Deoxy-3'-oxa-4'-thiocytidine and Their 5-Fluoro Analogues <i>in Vitro</i> ," <i>J. of Med. Chem.</i> , 38(1):1-4 (1995)
	GE	OHNO, <i>et al.</i> , "Synthetic Studies on Biologically Active Natural Products by a Chemicoenzymatic Approach," <i>Tet. Letters</i> , 40:145-152 (1984)
	GF	PAFF, <i>et al.</i> , "Intracellular Metabolism of (-)- and (+)-cis-5-Fluoro-1-[2-(Hydroxymethyl)-1,3-Oxathiolan-5-yl]Cytosine in HepG2 Derivative 2.2.15 (Subclone P5A) Cells," <i>Antimicrobial Agents and Chemotherapy</i> , 38(6):1230-1238 (June 1994)
	GG	PIRKLE <i>et al.</i> , "Chiral Stationary Phases for the Direct LC Separation of Enantiomers," <i>Advances in Chromatography</i> , Giddings, J.C., <i>et al.</i> , eds.: Marcel Dekker: New York, 1987; Vol. 27, Chap. 3, pp. 73-127
	GH	ROBERTS, <i>et al.</i> , "Enzymic Resolution of cis- and trans-4-hydroxycyclopent-2-enylmethanol..." <i>J. Chem. Soc., Perkin Trans.</i> , 1(10):2605-2607 (1991)
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	GK	SCHINAZI, R.F., <i>et al.</i> , "Insights into HIV Chemotherapy," <i>AIDS Research and Human Retroviruses</i> 8(6):963-990 (1992)
	GL	SCHINAZI, R.F., <i>et al.</i> , "Pharmacokinetics and Metabolism of Racemic 2',3'-Dideoxy-5-Fluoro 3'-Thiacytidine in Rhesus Monkeys," <i>Antimicrobial Agents and Chemotherapy</i> 36(11):2432-2438 (1992)
	GM	SCHINAZI, R.F., <i>et al.</i> , "Selective Inhibition of Human Immunodeficiency Viruses by Racemates and Enantiomers of cis-5-Fluoro-1-[2-(Hydroxymethyl)-1,3-Oxathiolan-5-yl]Cytosine," <i>Antimicrobial Agents and Chemotherapy</i> 36(11):2423-2431 (1992)
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	HA	SHEWACH, <i>et al.</i> , "Affinity of the antiviral enantiomers of oxathiolane cytosine nucleosides for human 2'-deoxycytidine kinase," <i>Biochem. Pharmacol.</i> , 45(7):1540-1543 (1993)
	HB	SOUDEYNS, H., <i>et al.</i> , "Anti-Human Immunodeficiency Virus Type 1 Activity and In Vitro Toxicity of 2'-Deoxy-3'-Thiacytidine (BCH- 189), a Novel Heterocyclic Nucleoside Analog," <i>Antimicrobial Agents and Chemotherapy</i> , 35(7):1386-1390 (1991)
	HC	STORER, R., <i>et al.</i> , "The Resolution and Absolute Stereochemistry of the Enantiomers of <i>cis</i> -1-[2-(Hydromethyl)- 1,3-Oxathiolan-5-yl]cytosine (BCH 189): Equipotent Anti-HIV Agents," <i>Nucleosides & Nucleotides</i> , 12(2):225-236 (1993).
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